EXHIBIT 3

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JOSEPH CACACCIO, CHARLENE NASS, MARZANNA GLAB, MARY McLEAN, ASHA LAMY and JAY MEADER; individually and on behalf of all others similarly situated, Plaintiffs, v. MYLAN PHARMACEUTICALS, INC., MYLAN N.V., and RITE AID CORPORATION, Defendants.	Civil Action No. 1:19-cv-06841-RBK-JS **FIRST AMENDED CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiffs Joseph Cacaccio, Charlene Nass, James Childs, Suzanne Gilbertson, Marzanna Glab, Mary McLean, Lawrence Edwards, Asha Lamy, Jay Meader, Marlin Anderson, and James Lawson ("Plaintiffs"), bring this action on behalf of themselves and all others similarly situated against Defendants Mylan Pharmaceuticals, Inc. ("Mylan"), Mylan N.V. (collectively, "the Mylan Defendants"), and Rite Aid Corporation ("Rite Aid") (collectively, "Defendants"). Plaintiffs make the following allegations pursuant to the investigation of their counsel and based upon information and belief, except as to the allegations specifically pertaining to themselves, which are based on personal knowledge.

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

1. This is a class action lawsuit regarding the Mylan Defendants' and Rite Aid's manufacturing, distribution, and sale of valsartan-containing generic prescription medications contaminated with N-nitrosodiethylamine (NDEA), a carcinogenic and liver-damaging impurity.

2. Originally marketed under the brand name Diovan, valsartan is a prescription medication mainly used for the treatment of high blood pressure and congestive heart failure. However, due to manufacturing defects originating from the Mylan Defendants' overseas laboratories in India, the Mylan Defendants have voluntarily recalled all non-expired lots of their valsartan-containing medications because they have been found to contain NDEA.

3. NDEA is classified as a probable human carcinogen. Animal studies have revealed the carcinogenic nature of the compound.

4. On July 13, 2018, the U.S. Food & Drug Administration ("FDA") announced a voluntary recall of several brands of valsartan-containing generic medications. The recall traced back to a Chinese company, Zhejiang Huahai Pharmaceuticals, which supplied the active pharmaceutical ingredient, valsartan, to American subsidiaries, as well as other companies. The recall was due to the presence of N-nitrosodimethylamine (NDMA) in the recalled valsartan products. The FDA's notice states that "NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured."

5. Originally, the recall was thought to have been limited to manufacturing practices in China; however, over the next several months, recalls continued to expand to other overseas laboratories in India.

6. The widespread recalls caused the FDA to evaluate and test the valsartan-

containing medications, which led to the FDA finding an additional impurity, NDEA, in several of the recalled medications. On November 20, 2018, the Mylan Defendants announced a voluntary nationwide recall of fifteen (15) lots of their valsartan-containing medications. Plaintiffs were prescribed, purchased, and used valsartan-containing medications manufactured, distributed and sold by Defendants. The fifteen (15) lots of contaminated valsartan-containing medications manufactured and distributed by the Mylan Defendants are as follows:

NDC	Product Description	Strength	Size	Lot Number	Expiry
0378-1721-93	Amlodipine and Valsartan Tablets, USP	5mg/160mg	Bottles of 30	3066051	3/2019
0378-1722-93	Amlodipine and Valsartan Tablets, USP	10mg/160mg	Bottles of 30	3079500	1/2020
0378-1724-93	Amlodipine and Valsartan Tablets, USP	10mg/320mg	Bottles of 30	3061986	11/2018
0378-1724-93	Amlodipine and Valsartan Tablets, USP	10mg/320mg	Bottles of 30	3079709	1/2020
0378-1724-93	Amlodipine and Valsartan Tablets, USP	10mg/320mg	Bottles of 30	3077618	11/2019
0378-1724-93	Amlodipine and Valsartan Tablets, USP	10mg/320mg	Bottles of 30	3079708	1/2020

0378-5813-77	Valsartan Tablets, USP	80mg	Bottles of 90	3063782	1/2019
0378-5814-77	Valsartan Tablets, USP	160mg	Bottles of 90	3071352	7/2019
0378-5807-93	Valsartan Tablets, USP	40mg	Bottles of 30	3061169	11/2018
0378-5815-77	Valsartan Tablets, USP	320mg	Bottles of 90	3081499	3/2020
0378-5815-77	Valsartan Tablets, USP	320mg	Bottles of 90	3080009	2/2020
0378-5815-77	Valsartan Tablets, USP	320mg	Bottles of 90	3080010	2/2020
0378-5815-77	Valsartan Tablets, USP	320mg	Bottles of 90	3079205	1/2020
0378-6325-05	Valsartan and Hydrochlorothiazide Tablets, USP	320mg/25mg	Bottles of 500	3084886	2/2019
0378-6325-05	Valsartan and Hydrochlorothiazide Tablets, USP	320mg/25mg	Bottles of 500	3093804	12/2019

7. The FDA announced that the recall was "due to detected trace amounts of an

impurity, N-nitrosodiethylamine (NDEA) contained in the API Valsartan, USP, manufactured by [Defendant] Mylan Laboratories. NDEA is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen according to the International Agency for Research on Cancer (IARC)."

8. After issuing a limited recall on November 20, 2018, the Mylan Defendants expanded their voluntary "nationwide recall to include all lots of Valsartan-containing products within expiry."[1] This represents a total of 104 additional lots recalled.

9. At all times during the period alleged herein, Defendants represented and warranted to consumers that their generic VCDs were therapeutically equivalent to and otherwise the same as their respective Reference Listed Drugs ("RLDs"), namely, DIOVAN, DIOVAN HCT, EXFORGE, and EXFORGE HCT, were otherwise fit for their ordinary uses, and were otherwise manufactured and distributed in accordance with applicable laws and regulations.

The Mylan Defendants failed to promptly recall their valsartan medications, even after announcement of other recalls.

10. After several waves of recalls by other companies, on November 20, 2018, the Mylan Defendants issued a voluntary recall of fifteen (15) lots of their valsartan-containing medications. Later, on December 4, 2018, the Mylan Defendants expanded the recall to all non-expired lots of their valsartan-containing medication due to the presence of NDEA.

11. Previous recalls, such as the Camber Pharmaceuticals recall announced on August 8, 2018, implicated specific manufacturing facilities in India as a source of contaminated valsartan medication. Despite this warning, the Mylan Defendants failed to take immediate action.

[1] http://investor.mylan.com/news-releases/news-release-details/mylan-expands-its-voluntary-nationwide-recall-valsartan-tablets (last visited 12/4/18).

12. The Mylan Defendants failed to promptly recall their valsartan-containing medications for over four months after the initial recall was announced, and over three months after overseas laboratories in India were implicated. The Mylan Defendants failed to do so despite knowing that their valsartan-containing medication were also contaminated. It took the Mylan Defendants another two weeks to recall all non-expired lots of the medication due to the presence of NDEA.

13. The Mylan Defendants reaped a substantial windfall from this non-disclosure, as patients like Plaintiff Cacaccio and other class members were actually switched to Mylan's valsartan-containing medications from previously-recalled brands.

14. Not only did Mylan benefit from patients being switched to their medications, but during the same period the price per tablet more than doubled, further contributing to Mylan's windfall.[2] According to Reuters, "[t]he price of a 160 mg valsartan tablet rose to around 31 cents from 14 cents a month earlier." All the while, the Mylan Defendants were manufacturing and distributing valsartan-containing medication contaminated with NDEA.

15. Like NDMA, NDEA is acutely toxic when consumed orally.

The Mylan Defendants boast the quality and safety of their valsartan products, even though they are contaminated with NDEA and unfit for human use.

16. Generic drugs reach the market when the brand-name version of the drug comes off patent, and other competitors are able to seek approval for, market, and sell bioequivalent versions of the brand-name drug. These generic equivalents are supposed to be of equal quality and equal safety. According to the FDA, "[a]ll generic drugs approved by [the] FDA have the same high quality, strength, purity, and stability as brand-name drugs."

[2] https://www.reuters.com/article/us-health-valsartan/cost-of-blood-pressure-drug-surges-in-u-s-after-recall-idUSKCN1MQ2X8 (last visited 12/4/18).

17. Here, the valsartan-containing drugs manufactured by the Mylan Defendants are supposed to be equivalent to the brand-name drug, Diovan. However, they are not because they suffer from a manufacturing defect which caused the Mylan Defendants' generic valsartan to be contaminated with NDEA.

18. As such, the Mylan Defendants' valsartan-containing medications are neither safe nor of equal quality to the brand-name version of the medication.

19. Not only did the Mylan Defendants' valsartan-containing medications fail to live up to FDA standards, but the Mylan Defendants falsely boast of the quality and efficacy of their medications on their website, in their packaging, and other materials presented to the consumer, which were relied upon by Plaintiffs and Class members in deciding to purchase their valsartan-containing medication from the Mylan Defendants. Had Plaintiffs and Class members known the true nature of the medication, they would not have purchased the medication. Instead, they would have requested a different, non-contaminated brand.

20. For example, the Mylan Defendants boast on their website:

> Mylan applies one global quality standard across our facilities, and across our product line … regardless of market.
>
> At Mylan, whether it's a medication for millions or for a handful of people our priorities are to meet or exceed industry standards.
>
> Because there's nothing generic about our standards. **Our internal teams conduct reviews of all products, start to finish. No matter where in the world they are made**. In fact, we championed a law that empowers the FDA to biennially inspect all manufacturing facilities around the world that supply the U.S. market.
>
> To us, trust goes beyond our global quality standards. It's all about caring for the people who will be helped by what we do.

> Quality is at the heart of everything we do.[3]

21. These warranties by the Mylan Defendants are false. An internal review should have caught the manufacturing defect that caused their medications to be contaminated with NDEA, but it did not. In fact, it took over four months for the Mylan Defendants to issue a voluntary recall after the initial wave of recalls was announced. It took an additional two weeks for the Mylan Defendants to finally issue a full recall of all non-expired lots of its valsartan-containing medication on December 4, 2018.

22. The representations made by the Mylan Defendants regarding the quality of their medications was a material misrepresentation that was relied upon by Plaintiffs and Class Members.

23. Moreover, the Mylan Defendants make the following additional representations:

> Mylan offers one of the broadest portfolios of active pharmaceutical ingredients (API)—the ingredients responsible for the therapeutic effects of different medicines—to more than 100 countries.
>
> Quality begins at step one. Mylan uses an established testing and verification process to ensure the suitability of active ingredients used in our medicines.[4]

24. These representations are also false, as the Mylan Defendants' valsartan API is contaminated with carcinogenic NDEA, which testing should have revealed.

25. Shortly before the voluntary recall was announced by the FDA on November 20, 2018, the FDA issued a Warning Letter to Mylan, "summariz[ing] significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals."[5]

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[3] http://www.mylan.com/en/products/quality (last visited 12/4/18).
[4] http://www.mylan.com/en/products/active-pharmaceutical-ingredients (last visited 12/4/18).
[5] https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm626360.htm (last visited 12/4/18).

26. The documented regulatory violations included failure to "clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, **quality, or purity** of the drug product beyond the official or other established requirements." (Emphasis added). Further, Mylan failed to "follow written procedures for production and process control designed to assure that the drug products [it] manufacture[s] have the identity, strength, quality, and purity they purport or are represented to possess, and to record and justify any deviations from them."

27. The FDA noted in its letter that Mylan has committed multiple similar violations at multiple sites. The FDA stated:

> FDA cited similar CGMP violations at this and other facilities in your company's network. Since 2015, FDA has taken the following actions in response to CGMP violations at Mylan facilities.
>
> • On August 6, 2015, three Mylan facilities (FEI No. 3003813519, FEI No. 3007512701, and FEI No. 3007648351) were issued a combined Warning Letter for, among other things, inadequate controls for manufacturing sterile drugs; failure to establish scientifically sound and appropriate laboratory controls; and failure to thoroughly investigate unexplained discrepancies.
>
> • On April 3, 2017, Mylan Laboratories, Ltd., FEI No. 3005587313, was issued a Warning Letter for, among other things, invalidating numerous initial OOS assay results without sufficient investigations to determine the root cause of the initial failure.

28. Because of these repeat and uncorrected violations, the FDA recommended that Mylan engage an independent third party CGMP consultant.

Plaintiffs and Class Members were harmed by purchasing and consuming contaminated valsartan-containing medications manufactured, distributed, and sold by Defendants.

29. Plaintiffs and the Class were injured by the full purchase price of their valsartan-containing medications. These medications are worthless, as they are contaminated with

carcinogenic and harmful NDEA, and therefore and are not fit for human consumption. Indeed, Plaintiffs have been instructed to immediately stop using the medication, and have been instructed to return the remaining medication for another, non-contaminated brand. Plaintiffs and the Class are further entitled to statutory damages, damages for the injury sustained in consuming high levels of acutely-toxic NDEA, and for damages related to Defendants' conduct.

30. Plaintiffs bring this action on behalf of themselves and Class Members for equitable relief and to recover damages and restitution for: (i) breach of express warranty; (ii) breach of the implied warranty of merchantability; (iii) violation of New York's General Business Law § 349; (iv) violation of New York's General Business Law § 350; (v) unjust enrichment; (vi) fraudulent concealment; (vii) fraud; (viii) conversion; (ix) strict products liability; (x) gross negligence; (xi) negligence; and (xii) battery.

PARTIES

31. Plaintiff Joseph Cacaccio is a citizen of New York who resides in Levittown, New York. Plaintiff Cacaccio was prescribed, purchased, and consumed recalled valsartan-containing medication manufactured and distributed by the Mylan Defendants, and sold by Defendant Rite Aid. Plaintiff Cacaccio purchased valsartan medication bearing NDC number 0378-5814-77, a 160 mg dose. Plaintiff Cacaccio paid a co-pay of $14.47 for the medication. Plaintiff Cacaccio originally learned about the valsartan recall by receiving a letter dated November 23, 2018 from Defendant Rite Aid, which informed him that the Mylan Defendants were recalling his medication "due to trace amounts of an impurity, N-nitrosodeithylamine (NDEA) contained in an active pharmaceutical ingredient (API) in Valsartan, USP manufactured by [Defendant] Mylan Laboratories Limited." Further investigation revealed that Plaintiff Cacaccio has been using the contaminated valsartan manufactured and distributed by the Mylan Defendants for

some time. When purchasing his valsartan-containing medications from the Mylan Defendants and Rite Aid, Plaintiff Cacaccio reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were properly manufactured and free from contaminants and defects. Plaintiff Cacaccio relied on these representations and warranties in deciding to purchase his valsartan-containing medications from the Mylan Defendants and Rite Aid, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased his valsartan-containing medications from the Mylan Defendants and Rite Aid if he had known that they were not, in fact, properly manufactured and free from contaminants and defects. Plaintiff Cacaccio understood that in making the sale, Rite Aid was acting with the knowledge and approval of the Mylan Defendants and/or as the agent of the Mylan Defendants. Plaintiff Cacaccio also understood that each purchase involved a direct transaction between himself and the Mylan Defendants, because his medication came with packaging and other materials prepared by the Mylan Defendants, including representations and warranties that his medications were properly manufactured and free from contaminants and defects.

32. Plaintiff Charlene Nass is a Pennsylvania resident and citizen. During the class period, Plaintiff Nass paid money for one or more of Defendants' valsartan-containing drugs (VCDs), including VCDs manufactured, distributed, and/or sold by the Mylan Defendants. Defendants expressly and impliedly warranted to Plaintiff Nass that their generic VCD products were the same as their RLDs. In fact, Plaintiff Nass purchased a product that was not the same as the RLD. Had Plaintiff Nass known the product was not the same as the RLD, Plaintiff Nass would not have paid for Defendants' VCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Nass would not have paid for

Defendants' VCDs.

33. Plaintiff James Childs is a New Jersey resident and citizen. During the class period, Plaintiff Childs paid money for one or more of the Mylan Defendants' VCDs, including VCDs manufactured, distributed, and/or sold by the Mylan Defendants. The Mylan Defendants expressly and impliedly warranted to Plaintiff Childs that their generic VCD products were the same as their RLDs. In fact, Plaintiff purchased a product that was not the same as the RLD. Had Plaintiff Childs known the product was not the same as the RLD, Plaintiff Childs would not have paid for the Mylan Defendants' VCDs. Likewise, had the Mylan Defendants' deception about the impurities within their products been made known earlier, Plaintiff Childs would not have paid for Defendants' VCDs.

34. Plaintiff Suzanne Gilbertson is a Virginia resident and citizen. During the class period, Plaintiff Gilbertson paid money for one or more of the Mylan Defendants' VCDs, including VCDs manufactured, distributed, and/or sold by the Mylan Defendants (as defined infra). The Mylan Defendants expressly and impliedly warranted to Plaintiff Gilbertson that their generic VCD products were the same as their RLDs. In fact, Plaintiff purchased a product that was not the same as the RLD. Had Plaintiff Gilbertson known the product was not the same as the RLD, Plaintiff Gilbertson would not have paid for the Mylan Defendants' VCDs. Likewise, had the Mylan Defendants' deception about the impurities within their products been made known earlier, Plaintiff Gilbertson would not have paid for the Mylan Defendants' VCDs.

35. Plaintiff Marzanna Glab is a New Jersey resident and citizen. During the class period, Plaintiff Glab paid money for one or more of the Mylan Defendants' VCDs, including VCDs manufactured, distributed, and/or sold by the Mylan Defendants. The Mylan Defendants expressly and impliedly warranted to Plaintiff Glab that their generic VCD products were the

same as their RLDs. In fact, Plaintiff purchased a product that was not the same as the RLD. Had Plaintiff Glab known the product was not the same as the RLD, Plaintiff Glab would not have paid for the Mylan Defendants' VCDs. Likewise, had the Mylan Defendants' deception about the impurities within their products been made known earlier, Plaintiff Glab would not have paid for the Mylan Defendants' VCDs.

36. Plaintiff Mary McLean is a Virginia resident and citizen. During the class period, Plaintiff McLean paid money for one or more of the Mylan Defendants' VCDs, including VCDs manufactured, distributed, and/or sold by the Mylan Defendants. The Mylan Defendants expressly and impliedly warranted to Plaintiff McLean that their generic VCD products were the same as their RLDs. In fact, Plaintiff McLean purchased a product that was not the same as the RLD. Had Plaintiff McLean known the product was not the same as the RLD, Plaintiff McLean would not have paid for the Mylan Defendants' VCDs. Likewise, had the Mylan Defendants' deception about the impurities within their products been made known earlier, Plaintiff McLean would not have paid for Defendants' VCDs.

37. Plaintiff Lawrence Edwards is a Georgia resident and citizen. During the class period, Plaintiff Edwards paid money for one or more of the Mylan Defendants' VCDs, including VCDs manufactured, distributed, and/or sold by the Mylan Defendants. The Mylan Defendants expressly and impliedly warranted to Plaintiff Edwards that their generic VCD products were the same as their RLDs. In fact, Plaintiff purchased a product that was not the same as the RLD. Had Plaintiff Edwards known the product was not the same as the RLD, Plaintiff Edwards would not have paid for the Mylan Defendants' VCDs. Likewise, had the Mylan Defendants' deception about the impurities within their products been made known earlier, Plaintiff Edwards would not have paid for the Mylan Defendants' VCDs.

38. Plaintiff Asha Lamy is an Alabama resident and citizen. During the class period, Plaintiff Lamy paid money for one or more of the Mylan Defendants' VCDs, including VCDs manufactured, distributed, and/or sold by Mylan Defendants. The Mylan Defendants expressly and impliedly warranted to Plaintiff Lamy that their generic VCD products were the same as their RLDs. In fact, Plaintiff purchased a product that was not the same as the RLD. Had Plaintiff Lamy known the product was not the same as the RLD, Plaintiff Lamy would not have paid for the Mylan Defendants' VCDs. Likewise, had the Mylan Defendants' deception about the impurities within their products been made known earlier, Plaintiff Lamy would not have paid for the Mylan Defendants' VCDs.

39. Plaintiff Jay Meader is a California resident and citizen. During the class period, Plaintiff Meader paid money for one or more of the Mylan Defendants' VCDs, including VCDs manufactured, distributed, and/or sold by the Mylan Defendants. The Mylan Defendants expressly and impliedly warranted to Plaintiff Meader that their respective generic VCD products were the same as their RLDs. In fact, Plaintiff purchased a product that was not the same as the RLD. Had Plaintiff Meader known the product was not the same as the RLD, Plaintiff Meader would not have paid for the Mylan Defendants' VCDs. Likewise, had the Mylan Defendants' deception about the impurities within their products been made known earlier, Plaintiff Meader would not have paid for the Mylan Defendants' VCDs.

40. Plaintiff Marlin Anderson is an Illinois resident and citizen. During the class period, Plaintiff Anderson paid money for one or more of the Mylan Defendants' VCDs, including VCDs manufactured, distributed, and/or sold by the Mylan Defendants. The Mylan Defendants expressly and impliedly warranted to Plaintiff Anderson that their respective generic VCD products were the same as their RLDs. In fact, Plaintiff purchased a product that was not

the same as the RLD. Had Plaintiff Anderson known the product was not the same as the RLD, Plaintiff Anderson would not have paid for the Mylan Defendants' VCDs. Likewise, had the Mylan Defendants' deception about the impurities within their products been made known earlier, Plaintiff Anderson would not have paid for the Mylan Defendants' VCDs.

41. Plaintiff James Lawson is a New Jersey resident and citizen. During the class period, Plaintiff Lawson paid money for one or more of the Mylan Defendants' VCDs, including VCDs manufactured, distributed, and/or sold by the Mylan Defendants. The Mylan Defendants expressly and impliedly warranted to Plaintiff Lawson that their respective generic VCD products were the same as their RLDs. In fact, Plaintiff purchased a product that was not the same as the RLD. Had Plaintiff Lawson known the product was not the same as the RLD, Plaintiff Lawson would not have paid for the Mylan Defendants' VCDs. Likewise, had the Mylan Defendants' deception about the impurities within their products been made known earlier, Plaintiff Lawson would not have paid for the Mylan Defendants' VCDs.

42. Defendant Mylan Pharmaceuticals, Inc. is a corporation organized under the laws of the State of Delaware and maintains its principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317. Defendant Mylan Pharmaceuticals, Inc. conducts substantial business in the State of New York, and nationwide. Defendant Mylan Pharmaceuticals, Inc. has been engaged in the manufacturing, sale, and distribution of contaminated generic valsartan in the United States, including in New York. Defendant Mylan Pharmaceuticals, Inc. is, upon information and belief, the United States subsidiary of Mylan N.V. Defendant Mylan Pharmaceuticals, Inc. acts as the agent and alter ego of Mylan N.V.

43. Defendant Mylan N.V. is a global generic and specialty pharmaceuticals company registered in the Netherlands, with its global headquarters at 1000 Mylan Boulevard,

Canonsburg, Pennsylvania 15317. Defendant Mylan N.V. conducts substantial business in New York, and nationwide. Defendant Mylan N.V. has been engaged in the manufacturing, sale, and distribution of contaminated generic valsartan in the United States, including in the State of New York. Upon information and belief, Mylan N.V. is the parent company of U.S.-based Mylan Pharmaceuticals, Inc., and India-based Mylan Laboratories, Ltd.

44. Defendant Rite Aid Corporation is a corporation organized under the laws of the State of Delaware and maintains its principal place of business at 30 Hunter Lane, Camp Hill, Pennsylvania 17011. Defendant Rite Aid Corporation sells the Mylan Defendants' valsartan-containing medication throughout the United States, and specifically in the State of New York. Plaintiff Joseph Cacaccio purchased his valsartan-containing medication at a Rite Aid location in Levittown, New York.

JURISDICTION AND VENUE

45. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below, is a citizen of a different state than Defendants, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds $5,000,000 exclusive of interest and costs.

46. Venue is proper in the Eastern District of New York pursuant to 28 U.S.C. § 1391 because many of the acts and transactions giving rise to this action occurred in the Eastern District of New York, Plaintiff Cacaccio resides in the Eastern District of New York, and because Defendants (a) are authorized to conduct business in the Eastern District of New York and have intentionally availed themselves of the laws and markets within the Eastern District of New York through the promotion, marketing, distribution, and sale of contaminated valsartan-

containing medications in the Eastern District of New York; (b) conduct substantial business in the Eastern District of New York; and (c) are subject to personal jurisdiction in the Eastern District of New York. This matter has been consolidated in the District of New Jersey for pre-trial proceedings.

47. Venue is proper in this District on account of the MDL consolidation pursuant to 28 U.S.C. § 1407 and because: Defendants reside in this District, 28 U.S.C. § 1391(b)(1); because "a substantial part of the events or omissions giving rise to the claim occurred" in this District, 28 U.S.C. § 1391(b)(2); and because Defendants are subject to the personal jurisdiction of this Court, 28 U.S.C. § 1391(b)(3).

CLASS ALLEGATIONS

48. Plaintiffs seek to represent a class defined as all persons in the United States who purchased or paid for valsartan-containing medications that are contaminated with NDEA (the "Nationwide Class"). Specifically excluded from the Class are persons who made such purchase for the purpose of resale, Defendants, Defendants' officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint venturers, or entities controlled by Defendants, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendants and/or Defendants' officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

49. Plaintiff Cacaccio also seeks to represent a subclass of all Class members who purchased valsartan-containing medications in New York (the "New York Subclass").

50. Plaintiff Nass also seeks to represent a subclass of all Class members who purchased valsartan-containing medications in Pennsylvania (the "Pennsylvania Subclass").

51. Plaintiffs Childs, Glab and Lawson also seek to represent a subclass of all Class

members who purchased valsartan-containing medications in New Jersey (the "New Jersey Subclass").

52. Plaintiffs Gilbertson and McLean also seek to represent a subclass of all Class members who purchased valsartan-containing medications in Virginia (the "Virginia Subclass").

53. Plaintiff Edwards also seeks to represent a subclass of all Class members who purchased valsartan-containing medications in Georgia (the "Georgia Subclass").

54. Plaintiff Lamy also seeks to represent a subclass of all Class members who purchased valsartan-containing medications in Alabama (the "Alabama Subclass").

55. Plaintiff Meader also seeks to represent a subclass of all Class members who purchased valsartan-containing medications in California (the "California Subclass").

56. Plaintiff Anderson also seeks to represent a subclass of all Class members who purchased valsartan-containing medications in Illinois (the "Illinois Subclass").

57. The Nationwide Class and state subclasses are collectively referred to as "the Class."

58. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class may be expanded or narrowed by amendment or amended complaint.

59. **Numerosity.** The members of the Class are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiffs reasonably estimate that there are hundreds of thousands of members in the Class. Although the precise number of Class members is unknown to Plaintiff, the true number of Class members is known by Defendants. More specifically, Defendants maintain databases that contain the following information: (i) the name of each Class member

who was prescribed the contaminated medication; (ii) the address of each Class member; and (iii) each Class member's payment information related to the contaminated medication. Thus, Class members may be identified and notified of the pendency of this action by U.S. Mail, electronic mail, and/or published notice, as is customarily done in consumer class actions.

60. **Existence and predominance of common questions of law and fact.** Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting only individual Class members. These common legal and factual questions include, but are not limited to, the following:

(a) whether the valsartan-containing medications manufactured, distributed, and sold by Defendants were in fact contaminated with NDEA, thereby breaching the express and implied warranties made by Defendants and making the medications unfit for human consumption and therefore unfit for their intended purpose, and constituting a clear manufacturing defect for purposes of strict liability and negligence, as well as battery as to the victims of the contaminated medication;

(b) whether Defendants knew or should have known that the valsartan-containing medications were in fact contaminated with NDEA prior to the recall, thereby constituting fraud and/or fraudulent concealment, and negligence or gross negligence;

(c) whether Defendants have unlawfully converted money from Plaintiffs and the Class;

(d) whether Defendants are liable to Plaintiffs and the Class for unjust enrichment;

(e) whether Defendants are liable to Plaintiffs and the Class for fraudulent concealment;

(f) whether Defendants are liable to Plaintiffs and the Class for violations of New

York consumer-protection laws;

(g) whether Defendants are liable to Plaintiffs and the Class for breaches of express and implied warranties;

(h) whether Plaintiffs and the Class have sustained monetary loss and the proper measure of that loss;

(i) whether Plaintiffs and the Class are entitled to declaratory and injunctive relief;

(j) whether Plaintiffs and the Class are entitled to restitution and disgorgement from Defendants; and

(k) whether the marketing, advertising, packaging, labeling, and other promotional materials for Defendants' valsartan-containing medications are deceptive.

61. **Typicality.** Plaintiffs' claims are typical of the claims of the other members of the Class in that Defendants mass marketed and sold contaminated medications to consumers throughout the United States. This contamination was present in all of the recalled medications manufactured, distributed, and sold by Defendants. Therefore, Defendants breached their express and implied warranties to Plaintiffs and Class members by manufacturing, distributing, and selling the contaminated valsartan medication. Plaintiffs' claims are typical in that all Class Members were uniformly harmed in purchasing and consuming the contaminated medications. Plaintiffs' claims are further typical in that Defendants deceived Plaintiffs in the very same manner as they deceived each member of the Class. Further, there are no defenses available to Defendants that are unique to Plaintiffs.

62. **Adequacy of Representation.** Plaintiffs will fairly and adequately protect the interests of the Class. Plaintiffs have retained counsel that is highly experienced in complex consumer class action litigation, and Plaintiffs intend to vigorously prosecute this action on

behalf of the Class. Furthermore, Plaintiffs have no interests that are antagonistic to those of the Class.

63. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members is relatively small compared to the burden and expense of individual litigation of their claims against Defendants. It would, thus, be virtually impossible for the Class, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

64. In the alternative, the Class may also be certified because:

(a) the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudication with respect to individual Class members that would establish incompatible standards of conduct for the Defendants;

(b) the prosecution of separate actions by individual Class members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

(c) Defendants have acted or refused to act on grounds generally applicable to the

Class as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

COUNT I
Breach Of Express Warranty
(On Behalf Of The Nationwide Class)

65. Plaintiffs hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

66. Plaintiffs bring this claim individually and on behalf of the members of the Class against Defendants.

67. Plaintiffs, and each member of the Class, formed a contract with Defendants at the time Plaintiffs and the other Class members purchased the contaminated valsartan medications. The terms of the contract include the promises and affirmations of fact made by Defendants on the contaminated medications' packaging and through marketing and advertising, including that the product would be of the same quality and equally as safe as the brand-name version of the medication. Defendants expressly warranted to Plaintiffs and Class members that the generic valsartan medications would be bioequivalent to the name-brand medication. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiffs and the members of the Class and Defendants.

68. Defendants further expressly warranted that the valsartan-containing medications would contain only what was stated on the label, and would not contain harmful and carcinogenic defects and impurities such as NDEA. Plaintiffs relied on the express warranty that their medications would contain only what was stated on the label, and that it would not be contaminated with impurities. These express warranties further formed the basis of the bargain,

and are part of the standardized contract between Plaintiffs and the members of the Class and Defendants.

69. Defendants purport, through their advertising, labeling, marketing and packaging to create an express warranty that the medications would be of the same quality and of equal safety as the name-brand medication.

70. Plaintiffs and the Class performed all conditions precedent to Defendants' liability under this contract when they purchased the contaminated medications.

71. Defendants breached express warranties about the contaminated medications and their qualities because Defendants' statements about the contaminated medications were false and the contaminated medications do not conform to Defendants' affirmations and promises described above.

72. Plaintiffs and each of the members of the Class would not have purchased the contaminated medications had they known the true nature of the contaminated medications' ingredients and what the contaminated medication contained (*i.e.*, NDEA).

73. As a result of Defendants' breaches of express warranties, Plaintiffs and each of the members of the Class have been damaged in the amount of the purchase price of the Product and any consequential damages resulting from the purchases.

74. On December 4, 2018 and April 26, 2019, prior to filing this action, Defendants were served with a pre-suit notice letters that complied in all respects with U.C.C. §§ 2-313, 2-607. Plaintiffs' counsel sent Defendants a letter advising them that they breached express warranties and demanded that they cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiffs' counsel's letters are attached hereto as **Exhibit A**.

COUNT II
Breach Of The Implied Warranty Of Merchantability
(On Behalf Of The Nationwide Class)

75. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

76. Plaintiffs bring this claim individually and on behalf of the members of the Class against Defendants.

77. Defendants, as the designers, manufacturers, marketers, distributors, and/or sellers, impliedly warranted that the valsartan-containing medications (i) contained no NDEA and (ii) are generally recognized as safe for human consumption.

78. Defendants breached the warranty implied in the contract for the sale of the contaminated valsartan-containing medications because they could not pass without objection in the trade under the contract description, the goods were not of fair average quality within the description, and the goods were unfit for their intended and ordinary purpose because the valsartan-containing medications manufactured, distributed, and sold by Defendants were contaminated with carcinogenic NDEA, and as such are not generally recognized as safe for human consumption. As a result, Plaintiffs and Class members did not receive the goods as impliedly warranted by Defendants to be merchantable.

79. Plaintiffs and Class members purchased the valsartan-containing medications in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

80. The valsartan-containing medications were not altered by Plaintiffs or Class members.

81. The valsartan-containing medications were defective when they left the exclusive

control of Defendants.

82. Defendants knew that the valsartan-containing medications would be purchased and used without additional testing by Plaintiffs and Class members.

83. The contaminated valsartan medications were defectively manufactured and unfit for their intended purpose, and Plaintiffs and Class members did not receive the goods as warranted.

84. As a direct and proximate cause of Defendants' breach of the implied warranty of merchantability, Plaintiffs and Class members have been injured and harmed because: (a) they would not have purchased the valsartan-containing medications on the same terms if they knew that the products contained NDEA, and are not generally recognized as safe for human consumption; and (b) the valsartan-containing medications do not have the characteristics, ingredients, uses, or benefits as promised by Defendants.

COUNT III
Violation Of New York's General Business Law § 349
(On Behalf Of The New York Subclass)

85. Plaintiffs hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

86. Plaintiff Cacaccio brings this claim individually and on behalf of the members of the proposed New York Subclass.

87. New York's General Business Law § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

88. In their sale of goods throughout the State of New York, Defendants conduct business and trade within the meaning and intendment of New York's General Business Law § 349.

89. Plaintiff Cacaccio and members of the Subclass are consumers who purchased products from Defendants for their personal use.

90. By the acts and conduct alleged herein, Defendants have engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, misrepresenting that the valsartan-containing medications (i) contained no NDEA or other harmful impurities, and (ii) are generally recognized as safe for human consumption (the "Misrepresentations").

91. The foregoing deceptive acts and practices were directed at consumers.

92. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and quality of the valsartan-containing medications manufactured, distributed, and sold by Defendants to induce consumers to purchase the same.

93. By reason of this conduct, Defendants engaged in deceptive conduct in violation of New York's General Business Law.

94. Defendants' actions are the direct, foreseeable, and proximate cause of the damages that Plaintiff Caccacio and members of the Subclass have sustained from having paid for and consumed Defendants' products.

95. As a result of Defendants' violations, Plaintiff Cacaccio and members of the Subclass have suffered damages because: (a) they would not have purchased Defendants' valsartan-containing medications on the same terms if they knew that the products contained NDEA, and are not generally recognized as safe for human consumption; and (b) Defendants' valsartan products do not have the characteristics, ingredients, uses, or benefits promised.

96. On behalf of himself and other members of the Subclass, Plaintiff Cacaccioand the New York Subclass seek to recover their actual damages or fifty dollars, whichever is

greater, three times actual damages, and reasonable attorneys' fees.

COUNT IV
Violation Of New York's General Business Law § 350
(On Behalf Of The New York Subclass)

97. Plaintiffs hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

98. Plaintiff Cacaccio brings this claim individually and on behalf of the members of the New York Subclass against Defendants.

99. Based on the foregoing, Defendants engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of Section 350 of the New York GBL.

100. Defendants' false, misleading, and deceptive statements and representations of fact, including but not limited to the Misrepresentations, were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

101. Defendants' false, misleading, and deceptive statements and representations of fact, including but not limited to the Misrepresentations, have resulted in consumer injury or harm to the public interest.

102. Plaintiff Cacaccioand members of the New York Subclass have been injured because: (a) they would not have purchased the contaminated valsartan-containing medication if they had known that the medications contained carcinogenic NDEA; and (b) the medications do not have the characteristics, uses, or benefits as promised, namely that the medications were contaminated with NDEA. As a result, Plaintiff Cacaccio and members of the New York Subclass have been damaged in the full amount of the purchase price of the medications.

103. As a result of Defendants' false, misleading, and deceptive statements and representations of fact, including but not limited to the Misrepresentations, Plaintiff Cacaccio has

suffered and will continue to suffer economic injury.

104. Plaintiff Cacaccio and members of the New York Subclass suffered an ascertainable loss caused by Defendants' Misrepresentations because they paid more for the medications than they would have had they known the truth about the Products (*i.e.* the full purchase price).

105. On behalf of himself and other members of the New York Subclass, Plaintiff Cacaccio seeks to enjoin the unlawful acts and practices described herein, to recover his actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT V
Unjust Enrichment
(On Behalf Of The Nationwide Class)

106. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

107. Plaintiffs bring this claim individually and on behalf of the members of the Class against Defendants.

108. Plaintiffs and the Class conferred a benefit on Defendants in the form of monies paid to purchase Defendants' contaminated valsartan medications.

109. Defendants voluntarily accepted and retained this benefit.

110. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for contaminated medications unfit for human use, it would be unjust and inequitable for the Defendants to retain it without paying the value thereof.

COUNT VI
Fraudulent Concealment
(On Behalf Of The Nationwide Class)

111. Plaintiffs hereby incorporate by reference the allegations contained in all

preceding paragraphs of this complaint.

112. Plaintiffs bring this claim individually and on behalf of the members of the Class against Defendants.

113. Defendants had a duty to disclose material facts to Plaintiffs and the Class given their relationship as contracting parties and intended users of the contaminated valsartan medications. Defendants also had a duty to disclose material facts to Plaintiffs and the Class, namely that they were in fact manufacturing, distributing, and selling harmful and contaminated medications unfit for human consumption, because Defendants had superior knowledge such that the transactions without the disclosure were rendered inherently unfair.

114. Defendants possessed knowledge of these material facts. In fact, Defendants failed to announce a recall for over four months after the initial recall of valsartan medications was announced, and failed to effectuate a full recall until two weeks after their initial recall of only fifteen (15) lots of the medication. Further, reports from government agencies reveal that this contamination may date as far back as 2012. During the time that Defendants concealed the contamination, Plaintiffs and Class members were using the medication without knowing it contained the harmful impurity NDEA. In fact, Plaintiff Cacaccio was switched to the Mylan Defendants' valsartan medication from another recalled brand, under the mistaken belief that it was safe for human use, when in fact it was not.

115. Defendants failed to discharge their duty to disclose these materials facts.

116. In so failing to disclose these material facts to Plaintiffs and the Class, Defendants intended to hide from Plaintiffs and the Class that they were purchasing and consuming medications with harmful impurities that were unfit for human use, and thus acted with scienter and/or an intent to defraud. As discussed above, Defendants obtained a substantial financial

benefit as a result of their fraudulent concealment of the contaminated nature of the medication.

117. Plaintiffs and the Class reasonably relied on Defendants' failure to disclose insofar as they would not have purchased the contaminated valsartan medication manufactured, distributed, and sold by Defendants had they known it was contaminated with NDEA.

118. As a direct and proximate cause of Defendants' fraudulent concealment, Plaintiffs and the Class suffered damages in the amount of monies paid for the defective medication.

119. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT VII
Fraud
(On Behalf Of The Nationwide Class)

120. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

121. Plaintiffs bring this claim individually and on behalf of the members of the Class against Defendants.

122. As discussed above, Defendants provided Plaintiffs and Class members with false or misleading material information about the valsartan medications manufactured, distributed, and sold by Defendants. For example, the Mylan Defendants boast on their website:

> Mylan applies one global quality standard across our facilities, and across our product line … regardless of market.
>
> At Mylan, whether it's a medication for millions or for a handful of people our priorities are to meet or exceed industry standards.
>
> Because there's nothing generic about our standards. **Our internal teams conduct reviews of all products, start to finish. No matter where in the world they are made**. In fact, we championed a law that empowers the FDA to biennially inspect all manufacturing facilities around the world that supply the U.S. market.

> To us, trust goes beyond our global quality standards. It's all about caring for the people who will be helped by what we do.
>
> Quality is at the heart of everything we do.

And

> Mylan offers one of the broadest portfolios of active pharmaceutical ingredients (API)—the ingredients responsible for the therapeutic effects of different medicines—to more than 100 countries.
>
> Quality begins at step one. Mylan uses an established testing and verification process to ensure the suitability of active ingredients used in our medicines.

123. As indicated above, however, these representations are false as its valsartan medications were contaminated with carcinogenic NDEA.

124. Defendants represented, through their advertising, labeling, marketing and packaging that the medications would be of the same quality and of equal safety as the name-brand medication. In short, Defendants represented that their generic valsartan medication would be the bioequivalent of the name-brand medication, Diovan. It was not.

125. The misrepresentations and omissions of material fact made by Defendants, upon which Plaintiffs and Class members reasonably and justifiably relied, were intended to induce and actually induced Plaintiffs and Class members to purchase these contaminated valsartan-containing medications.

126. Defendants knew that the medications contained the harmful impurity NDEA, but continued to manufacture them, even after other manufacturers from India voluntarily recalled their products. In fact, reports from government agencies reveal that this contamination can date back to 2012. During that time that Defendants knew of but failed to disclose the contamination, Plaintiffs and Class Members were using the medication without knowing it contained the

harmful impurity NDEA.

127. The fraudulent actions of Defendants caused damage to Plaintiffs and Class members, who are entitled to damages and other legal and equitable relief as a result.

128. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT VIII
Conversion
(On Behalf Of The Nationwide Class)

129. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

130. Plaintiffs bring this claim individually and on behalf of the members of the Class against Defendants.

131. Plaintiffs and the Class have an ownership right to the monies paid for the contaminated medication manufactured, distributed, and sold by Defendants.

132. Defendants have wrongly asserted dominion over the payments illegally diverted to them for the contaminated medication. Defendants have done so every time that Plaintiffs and the Class have paid to have their prescriptions filled.

133. As a direct and proximate cause of Defendants' conversion, Plaintiffs and the Class suffered damages in the amount of the payments made for each time they filled their prescriptions.

COUNT IX
Strict Liability – Manufacturing Defect
(On Behalf Of The Nationwide Class)

134. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

135. Plaintiffs bring this claim individually and on behalf of the members of the Class against Defendants.

136. The NDEA impurity contained in the Defendants' medications was a mishap in the manufacturing process which led to the valsartan medications containing the harmful impurity NDEA. NDEA was not intended to be included in the medication; it was an impurity that was created due to an error in the manufacturing process.

137. Due to the NDEA impurity, the product was not reasonably safe as marketed because NDEA is a known carcinogen, and, according to the FDA, the level of NDEA in the effected medication far exceeded acceptable levels, warranting an immediate recall of the effected medication.

138. NDEA is acutely toxic and therefore immediately causes injury when ingested.

139. Plaintiffs and all Class members used the product for its intended purpose, meaning they used the product as prescribed by their respective doctors.

140. There is no way that Plaintiffs or Class members could have discovered the defect by exercising reasonable care. There was no way for Plaintiffs or Class Members to tell by visually observing, tasting, or smelling the medication that it was in fact contaminated with NDEA. Nothing short of laboratory tests (which should have been done by Defendants for quality control purposes) would have revealed the defect to the unsuspecting consumer.

141. Because Plaintiffs and Class members had no way of knowing that their medication was in fact contaminated, Plaintiffs and Class members could not have avoided the injury by exercising ordinary care.

142. Defendants were supposed to manufacture, distribute, and sell valsartan-containing medications without any harmful impurities such as NDEA. The valsartan

medications were not designed or intended to contain NDEA. These impurities resulted from a manufacturing defect which allowed the medication to become contaminated.

143. Plaintiffs and Class Members suffered harm as a result of consuming this contaminated medication. The ingestion of NDEA is acutely harmful. NDEA, when ingested orally, is immediately harmful to the liver, kidneys, and pulmonary function. "Acute toxicity refers to those adverse effects occurring following oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours." As such, NDEA causes harm as soon as it is consumed.

144. Importantly, Plaintiffs and Class members do not seek resolution of downstream effects of NDEA such as cancer or other individualized illnesses on a class-wide basis. Any such actions can and should be redressed on an individual basis as they arise. However, because of the acute toxicity of NDEA, Plaintiffs and class-members suffered a concrete and identical harm that can and should be addressed on a class-wide basis.

145. Because the valsartan medications manufactured, distributed, and sold by Defendants suffered from a manufacturing defect which caused Plaintiffs and Class members an immediate and concrete harm, Defendants are strictly liable to Plaintiffs and Class Members.

COUNT X
Gross Negligence
(On Behalf Of The Nationwide Class)

146. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

147. Plaintiffs bring this claim individually and on behalf of the members of the Class against Defendants.

148. Defendants owed a duty of care to Plaintiffs to manufacture, distribute, and sell

the subject valsartan medications free from harmful defects and impurities.

149. Defendants breached that duty by manufacturing, distributing, and selling valsartan medication contaminated with NDEA.

150. Plaintiffs and Class members were injured by ingesting an acutely toxic substance, to wit NDEA, which was negligently present in the valsartan medications manufactured, distributed, and sold by Defendants. Plaintiffs and Class members also suffered economic damages and emotional distress from the purchase and use of the valsartan-containing medications.

151. Importantly, Plaintiffs and the Class members do not seek resolution of downstream effects of NDEA such as cancer or other individualized illnesses on a class-wide basis. Any such actions can and should be redressed on an individual basis as they arise. However, because of the acute toxicity of NDEA, Plaintiffs and Class members suffered a concrete and identical harm that can and should be addressed on a class-wide basis.

152. For the reasons set forth at length above, Defendants' conduct evinces a reckless disregard for the rights of others, and strongly suggests intentional wrongdoing.

153. Because the valsartan medications manufactured, distributed, and sold by Defendants suffered from a harmful impurity constituting a breach of Defendants' duty to Plaintiffs and Class members, and because Defendants failed to act promptly to remediate the harmful impurity, Defendants are grossly negligent and are liable to Plaintiffs and Class members for all injuries proximately caused by Defendants' gross negligence.

COUNT XI
Negligence
(On Behalf Of The Nationwide Class)

154. Plaintiffs hereby incorporate by reference the allegations contained in all

preceding paragraphs of this complaint.

155. Plaintiffs bring this claim individually and on behalf of the members of the Class against Defendants.

156. Defendants owed a duty of care to Plaintiffs and Class members to manufacture, distribute, and sell the subject valsartan medications free from harmful defects and impurities.

157. Defendants breached that duty by manufacturing, distributing, and selling valsartan medication contaminated with NDEA.

158. Plaintiffs and Class members were injured by ingesting an acutely toxic substance, to wit NDEA, which was negligently present in the valsartan medications manufactured, distributed, and sold by Defendants.

159. Importantly, Plaintiffs and the Class members do not seek resolution of downstream effects of NDEA such as cancer or other individualized illnesses on a class-wide basis. Any such actions can and should be redressed on an individual basis as they arise. However, because of the acute toxicity of NDEA, Plaintiffs and Class members suffered a concrete and identical harm that can and should be addressed on a class-wide basis.

160. Because the valsartan medications manufactured, distributed, and sold by Defendants suffered from a harmful impurity constituting a breach of Defendants' duty to Plaintiffs and Class members, Defendants are negligent and are liable to Plaintiffs for all injuries proximately caused by Defendants' negligence.

161. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

162. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class against Defendants.

163. The Mylan Defendants owed a duty to Plaintiffs and the Class to ensure that the Valsartan product it sold in the United States was therapeutically equivalent to the brand name Diovan and/or complied with cGMPs and/or was not adulterated or contaminated.

164. The Mylan Defendants owed a duty to Plaintiffs and the Class because New York, and every other State, territory, and possession has adopted and/or adheres to federal cGMP and adulteration standards.

165. The Mylan Defendants failed to comply with federal cGMPs and/or federal adulteration standards.

166. As a result of the Mylan Defendants' failures to do so, the Mylan Defendants own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class.

167. As a direct and proximate result of the Mylan Defendants' negligent conduct, Plaintiffs and the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

COUNT XII
Battery
(On Behalf Of The Nationwide Class)

168. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

169. Plaintiffs bring this claim individually and on behalf of the members of the Class against Defendants.

170. Defendants manufactured, distributed, and sold the contaminated valsartan medication to Plaintiffs and Class members with the knowledge and intent that Plaintiffs and Class members would ingest the medication. Defendants thus had knowledge that the harmful medication would come into contact with the bodies of Plaintiffs and Class members.

171. The intended contact, i.e. the medication being ingested by Plaintiff, was harmful in nature because the medication contained the harmful impurity NDEA.

172. As such, Defendants committed an unlawful battery on Plaintiffs and Class members, who ingested the medication.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, seeks judgment against Defendants, as follows:

A. For an order certifying the Nationwide Class and the New York Subclass under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiffs as representative of the Class and Plaintiffs' attorneys as Class Counsel to represent the Class;

B. For an order declaring that the Defendants' conduct violates the statutes referenced herein;

C. For an order finding in favor of Plaintiffs, the Nationwide Class, and the New York Subclass on all counts asserted herein;

D. For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;

E. For prejudgment interest on all amounts awarded;

F. For an order of restitution and all other forms of equitable monetary relief;

G. For injunctive relief as pleaded or as the Court may deem proper; and

H. For an order awarding Plaintiffs and the Class their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of any and all issues in this action so triable of right.

Dated: December 14, 2020

Respectfully submitted,

BURSOR & FISHER, P.A.

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